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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,866	08/25/2003	Pierre Gauthier		1663

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7590

11/26/2007

EXAMINER

UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,866	Applicant(s) GAUTHIER, PIERRE	
	Examiner Thane Underdahl	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/8/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Restriction/Election

Applicant's response to the species election without traverse filed on 5/8/06 is acknowledged. The applicant elected Group II which includes claims 4-19. These claims will now be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. These claims, and in particular claim 4, uses the indefinite term of "substantially" when describing the relationships of the parts of this device. This term is indefinite since the claims and specification are drawn to a device for producing a section of tissue. The movement of these parts relative to each other appears to be rigid and require a high tolerance of design and machining which is not implied by the indefinite phrase substantially. Also the limitations of "piston component" and "sleeve component" is indefinite since it is unclear if the "components" include the whole piston and sleeve or simply a portion of it. Because claims 5-19 depend from indefinite claim 4 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 10 is indefinite since it defines that the sleeve and molding plate are in a "predetermined relationship relative to each other". The specification gives examples of how the molding plate and sleeve are positioned but the broad limitation of any

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predetermined relationship is unclear in absence of a concrete definition in the specification. Also the limitation of the locking component being provided with a "freezing aperture extending therethrough". The word "therethrough" is not found in common online dictionaries such as www.dictionary.com and www.m-w.com and is not clearly defined in the specification so this limitation is indefinite in the absence of a clear understanding of the term in relation to the locking component. Also the term "freezing aperture" is indefinite since it is not clear from the specification if the aperture is indeed itself freezing or is simply an opening for the passage of freezing fluid. Also it is unclear if the aperture is open to the tissue via a direct connection or is a convection-type freezing through the molding plate. Clarification is required.

Claim 12 and dependant claim 13 are indefinite because of the explanation of the position of the threads between the locking ring and the sleeve. The locking ring has an inner thread formed on its inner surface. The sleeve component has an outer thread formed on the outer surface. These two threads are supposed to engage. However if the locking ring has the threads on the inside, away from the sleeve, it would be impossible for the threads that are on the outside of the sleeve. The outside of the sleeve as defined by the previous claims 1 and 19 does not have contact with the locking ring. This is confusing to the Examiner who understands that the claims, as written, have the inside of the sleeve component in contact with the locking ring. Clarification is required.

Also claim 17 and its dependants are indefinite because they use the phrase "a rod external thread formed on said positioning rod". It is unclear what a "rod external

thread" is and how it modifies the positioning rod. Clarification is required. Also the phrase "a flange thread for threadably" is indefinite since this term is not a phrase commonly used in the art. Clarification is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-11 and 14-19 rejected under 35 U.S.C. 102(b) as being anticipated by Rada (U.S. Patent # 4752347).

These claims are for an apparatus to coat an excised tissue sample with a gel to form a block encasing the tissue margins. The apparatus having a piston and a tissue support. A sleeve component that has an inner and outer wall that defines a channel to guide the piston, via a longitudinal axis, down to the tissue sample. A molding plate, that is opposite of the descending piston, that provides an auxiliary surface that supports the tissue and provides a template for the gel block that will encapsulate the tissue. The sleeve component surrounds the boarder of the molding plate.

Rada teaches in Figures 20, 21 and 23 an apparatus that encapsulates a tissue sample (101) in a gel (179). The apparatus has a piston (168 and 167) and a sleeve that guides the piston (176 and 173) to an auxiliary surface (178, 107, 115) that supports the tissue sample, which is sandwiched between the piston and the auxiliary surface. The piston is perpendicular to the auxiliary surface and can be adjusted in a longitudinal direction as guided by the abutting sleeve to mold the sample block. A sealing ring (178) is placed around the tissue sample to contain the gel and tissue

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sample while being compressed by the piston. This collar locks the plate in the plate molding configuration. The collar is removable but will lock into place to make sure the mold maintains its shape (col 11 lines 10-20). Figures 21 and 23 teach that the sleeve has an aperture to allow the flow of a cryogenic liquid

Rada also teaches in Figures 3- 8 that the auxiliary surface can be a platform (22) with a gripping rod (25) that can position the piston axially in a mount. The tissue on this platform can be compressed by another piston (55) aligned and guided by two parallel pillars (58) and locked into place (48, also see col 6, lines 23-37). The gripping rod is smooth bored and can according to figures 3, 7 and 8 can be rotated 360 degrees in a supporting base plate that is upright (see Figure's 2 and 6).

Therefore the reference anticipates claims 4-11 and 14-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rada (U.S. Patent # 4752347).

The description and rejection of claims 4-11 and 14-19 are listed in the 35 U.S.C § 102(b) rejection above.

Claims 12 and 13 limit the locking ring of the invention.

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While Rada et al. teaches a locking ring that is abutted to the sleeve that do not teach that the sleeve or locking ring are threaded. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made. The idea that a circular collar is locked in place with a component that is complimentary shape via a threaded connection is well known in the art (i.e. nut and bolt). It is clear that the piston that makes up the molding plate and that is surrounded by the locking ring are complimentary in shape, in other words both components are round and fit snugly together (see figures 20-23). It would have been obvious to someone skilled in the art to use a locking collar that is a threaded ring to clamp onto the molding plate. Rada teach that the locking ring must be rigid and must be sealed with sufficient strength to allow the liquid embedding medium to surround the tissue without leaking (col 11, lines 10-20). One of ordinary skill in the art would recognize that a threaded sealed ring accomplishes this purpose since threaded sealed rings are well known in the art to be used in confining liquids to containers (i.e. Mason jars). Since the technique of confining a liquid via a threaded collar is well known in the art it would have been obvious to someone skilled in the art to use a threaded collar to confine the gel in the invention of Rada and achieve the same result after the molding process was complete (KSR vs. Teleflex).

Therefore the references listed above renders obvious claims 4-19.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims

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(MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

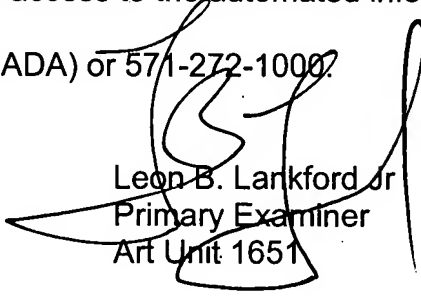
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651



Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651